<INSERT CANCER NAME> STRUCTURED REPORTING PROTOCOL

(*<Insert whether 1st, 2nd etc> Edition> <Insert year published here e.g. 2009>*)

<Based on the:

International Collaboration on Cancer Reporting (ICCR)

<<Cancer>> Dataset

www.ICCR-Cancer.org>

Core Document versions:

- *ICCR dataset: < insert name of ICCR dataset in which this protocol is based>*
- TNM Cancer Staging Manual *x*th edition. *State whether this is a reprint or includes any errata.*
- WHO Classification of Neoplasms of *xxxx. Year of publication*

<Amend with correct numbers>

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Disclaimer

The Royal College of Pathologists of Australasia ("College") has developed these protocols as an educational tool to assist pathologists in reporting of relevant information for specific cancers. <For 2nd edition protocols remove the following sentences: While each protocol includes "standards" and "guidelines" which are indicators of 'minimum requirements' and 'recommendations', the protocols are a first edition and have not been through a full cycle of use, review and refinement. Therefore, in this edition, the inclusion of "standards" and "guidelines" in each document are provided as an indication of the opinion of the relevant expert authoring group, but should not be regarded as definitive or as widely accepted peer professional opinion.> The use of these standards and guidelines is subject to the clinician's judgement in each individual case.

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Contents

Instructions for 'Contents'
Right click within the table of contents and select 'Update Field'. Choose the option 'Update entire table'.
Delete this box and its contents

Scope

Instructions for 'Scope'
Insert a concise summary (~150 words) that explains the purpose and application of the document, the techniques used and the intended audience.
Name the precise types of cancer and sample covered by the protocol
Specify any specimen types, anatomical sites etc that are excluded from the protocol.
Insert the following if appropriate: "In cases of multiple, or synchronous primary tumours, a separate protocol should be recorded for each tumour."
Delete this box and its contents

This protocol contains standards and guidelines for the preparation of structured reports for <<specimen type>> for <*Insert cancer type*>.

Structured reporting aims to improve the completeness and usability of pathology reports for clinicians, and improve decision support for cancer treatment. The protocol provides the framework for the reporting of any <*Insert cancer type*> cancer, whether as a minimum data set or fully comprehensive report.

<*Insert text, as necessary*>

Abbreviations

Instructions for 'Abbreviations'
Add abbreviations to the table below, as necessary (the table contains some blank rows; add more rows or delete, as required).
List abbreviations in alphabetical order in the table.
Give all abbreviations in full at first use in the text followed by the abbreviated form, in brackets; thereafter, use the abbreviation throughout the document.
Delete this box and its contents

AJCC	American Joint Committee on Cancer
IHC	Immunohistochemistry
IHI	Individual health identifier
LIS	Laboratory Information System
MRN	Medical Record Number
NHI	National Health Identifier (NZ)
PBS	Pharmaceutical Benefits Scheme
RCPA	Royal College of Pathologists of Australasia
TNM	tumour-node-metastasis
UHI	Unique Health Identifier
UICC	International Union Against Cancer
WHO	World Health Organization

Definitions

Instructions for 'Definitions'
Add definitions to the table below, as necessary (add rows as required).
Define any general or technical terms used in the protocol that may require more explanation.
List items in alphabetical order.
The definitions for standard, guideline and commentary given in the table below should remain because they explain the structure used to categorise the reporting items identified by the expert group that developed the protocol.
Delete this box and its contents

The table below provides definitions for general or technical terms used in this protocol. Readers should take particular note of the definitions for 'standard', 'guideline' and 'commentary', because these form the basis of the protocol.

Ancillary study	An ancillary study is any pathology investigation that may form part of a cancer pathology report but is not part of routine histological assessment.
Clinical information	Patient information required to inform pathological assessment, usually provided with the specimen request form, also referred to as "pre-test information".
Commentary	Commentary is text, diagrams or photographs that clarify the standards (see below) and guidelines (see below), provide examples and help with interpretation, where necessary (not every standard or guideline has commentary). Commentary is used to: • define the way an item should be reported, to foster reproducibility • explain why an item is included (e.g. how does the item assist with clinical management or prognosis of the specific cancer). • cite published evidence in support of the standard or guideline • state any exceptions to a standard or guideline. In this document, commentary is prefixed with 'CS' (for commentary on a standard) or 'CG' (for commentary on a guideline), numbered to be consistent with the relevant standard or guideline, and with sequential alphabetic lettering within each set of commentaries (eg CS1.01a, CG2.05b).

General commentary	General commentary is text that is not associated with a specific standard or guideline. It is used: • to provide a brief introduction to a chapter, if necessary • for items that are not standards or guidelines but are included in the protocol as items of potential importance, for which there is currently insufficient evidence to recommend their inclusion. (Note: in future reviews of protocols, such items may be reclassified as either standards or guidelines, in line with diagnostic and prognostic advances, following evidentiary review).
Guideline	Guidelines are recommendations; they are not mandatory, as indicated by the use of the word 'should'. Guidelines cover items that are unanimously agreed should be included in the dataset but are not supported by NHMRC level III-2 evidence.[1] These elements may be clinically important and recommended as good practice but are not yet validated or regularly used in patient management. Guidelines include key information other than that which is essential for clinical management, staging or prognosis of the cancer such as macroscopic observations and interpretation, which are fundamental to the histological diagnosis and conclusion eg macroscopic tumour details, block identification key, may be included as either required or recommended elements by consensus of the expert committee. Such findings are essential from a clinical governance perspective, because they provide a clear, evidentiary decision-making trail. Guidelines are not used for research items. In this document, guidelines are prefixed with 'G' and numbered consecutively within each chapter (eg G1.10).
Macroscopic findings	Measurements, or assessment of a biopsy specimen, made by the unaided eye.
Microscopic findings	In this document, the term 'microscopic findings' refers to histo-morphological assessment.
Predictive factor	A *predictive factor* is a measurement that is associated with response or lack of response to a particular therapy.
Prognostic factor	A *prognostic factor* is a measurement that is associated with clinical outcome in the absence of therapy or with the application of a standard therapy. It can be thought of as a measure of the natural history of the disease.

Standard	Standards are mandatory, as indicated by the use of the term 'must'. Standards are essential for the clinical management, staging or prognosis of the cancer. These elements will either have evidentiary support at Level III-2 or above (based on prognostic factors in the NHMRC levels of evidence[1] document). In rare circumstances, where level III-2 evidence is not available an element may be made a Standard where there is unanimous agreement in the expert committee. An appropriate staging system eg Pathological TNM staging would normally be included as a required element.These elements must be recorded and at the discretion of the pathologist included in the pathology report according to the needs of the recipient of the report. The summation of all standards represents the minimum dataset for the cancer. In this document, standards are prefixed with 'S' and numbered consecutively within each chapter (eg **S1.02**).
Structured report	A report format which utilises standard headings, definitions and nomenclature with required information.
Synoptic report	A structured report in condensed form (as a synopsis or precis).
Synthesis	Synthesis is the process in which two or more pre-existing elements are combined, resulting in the formation of something new. The Oxford dictionary defines synthesis as "the combination of components or elements to form a connected whole". In the context of structured pathology reporting, synthesis represents the integration and interpretation of information from two or more modalities to derive new information.

Introduction

Instructions for 'Introduction'
Write an introduction that includes the following information:
• a brief summary of the cancer type
• the importance of histopathological reporting for clinical management and prognosis in general, and specific to the cancer type (e.g. examples of different pathological findings leading to different treatment or management decisions)
• a summary of the benefits of structured reporting and the role of the International Collaboration on Cancer Reporting (ICCR) to international standardisation of structured reporting, including secondary benefits to research and patient care in the long term
• acknowledgment of key documentation used in the development process (e.g. existing guidelines, World Health Organization (WHO) reports)
• acknowledgement of any areas of uncertainty and method of dealing with them, if applicable
• a brief summary of changes since the last edition (e.g. a scientific breakthrough that has necessitated the inclusion of new data items).
Delete this box and its contents

<NAME> cancer

<Insert text about specific cancer >

Importance of histopathological reporting

The information contained within a pathology report includes prognostic information for the patient and treating clinical team. The content will assist in subsequent management, whether this may be surveillance, further surgery, radiotherapy or chemotherapy, or a combination of these modalities.

<Insert text, as necessary>

Benefits of structured reporting

The pathology report lays the foundation for a patient's cancer journey and conveys information which:

- Provides the definitive diagnosis
- Includes critical information for Tumour-Node-Metastasis (TNM) staging
- Evaluates the adequacy of the surgical excision
- Provides morphological and biological prognostic markers which determine personalised cancer therapy

However, the rapid growth in ancillary testing such as immunohistochemistry, flow cytometry, cytogenetics, and molecular studies, have made the task of

keeping abreast of advances on specific cancer investigations extremely difficult for pathologists. The use of structured reporting checklists by pathologists ensures that all key elements are included in the report specifically those which have clinical management, staging or prognostic implications. Consequently minimum or comprehensive datasets for the reporting of cancer have been developed[2,3] around the world. Both the United Kingdom,[4] and United States[5] have produced standardised cancer reporting protocols or "datasets" for national use for many years.

The use of cancer reporting checklists improves completeness and quality of cancer reporting and thereby ensures an improved outcome for cancer patients. This has long term cost implications for public health by ensuring the most effective and timely treatment based on accurate and complete information.

The use of a structured reporting format also facilitates easy extraction of the necessary information by secondary users of the information ie cancer registries.

International Collaboration on Cancer Reporting

The International Collaboration on Cancer Reporting (ICCR), founded in 2011 by the Australasian (RCPA), US (CAP) and UK (RCPath) Colleges of Pathology and the Canadian Association of Pathology (CAP-ACP) in association with the Canadian Partnership Against Cancer (CPAC), was established to explore the possibilities of a collaborative approach to the development of common, internationally standardised and evidence-based cancer reporting protocols for surgical pathology specimens.

The ICCR, recognising that standardised cancer datasets have been shown to provide significant benefits for patients and efficiencies for organisations through the ease and completeness of data capture[6-9] undertook to use the best international approaches and the knowledge and experience of expert pathologists, and produce cancer datasets which would ensure that cancer reports across the world will be of the same high quality – ensuring completeness, consistency, clarity, conciseness and above all, clinical utility.

Representatives from the four countries participating in the initial collaboration undertook a pilot project in 2011 to develop four cancer datasets - Lung, Melanoma, Prostate (Radical Prostatectomy), and Endometrium. Following on from the success of this pilot project, the ICCR was joined by the European Society of Pathology (ESP) in 2013 and in 2014 incorporated a not-for-profit organisation focussed on the development of internationally agreed evidence-based datasets developed by world leading experts. The ICCR Datasets are made freely available from its website www.ICCR-Cancer.org

Design of this protocol

This structured reporting protocol has been developed using the ICCR dataset on << cancer >> as the foundation.

This protocol includes all of the ICCR cancer dataset elements as well as additional information, elements and commentary as agreed by the RCPA expert

committee. It provides a comprehensive framework for the assessment and documentation of pathological features of cancers of the << cancer >>.

ICCR dataset elements for *<insert specific cancer name>* are included verbatim. ICCR Required elements are mandatory and therefore represented as standards in this document. ICCR Recommended elements, that is, those which are not mandatory but are recommended, may be included as guidelines or upgraded to a standard based on the consensus opinion of the local expert committee.

The ICCR elements are identified in each chapter with the ICCR logo placed before the Standard or Guideline number or bullet and the ICCR element description and commentary is boarded by a grey box as shown below:

G3.02	The intraglandular extent should be recorded as a percentage.

Additional commentary by the RCPA expert committee may be added to an ICCR element but is not included in the grey bordered area eg

G2.03	If present, the laterality of the lymph nodes submitted may be recorded as left, right or bilateral.
CS2.03a	If present, record site and number. All lymph node tissue should be submitted for histological examination.

Further information on the ICCR is available at www.iccr-cancer.org

Checklist

Consistency and speed of reporting is improved by the use of discrete data elements recorded from the checklist. Items suited to tick boxes are distinguished from more complex elements requiring free text or narrative. A structured or discrete approach to responses is favoured, however the pathologist is encouraged to include free text or narrative where necessary to document any other relevant issues, to give reasons for coming to a particular opinion and to explain any points of uncertainty.

Report format

The structure provided by the following chapters, headings and subheadings describes the elements of information and their groupings, but does not necessarily represent the format of either a pathology report (Chapter 7) or checklist (Chapter 6). These, and the structured pathology request form (Appendix 1) are templates that represent information from this protocol, organised and formatted differently to suit different purposes.

Key documentation

<Insert text or edit, as necessary>

- *Guidelines for Authors of Structured Cancer Pathology Reporting Protocols, Royal College of Pathologists of Austr*alasia, 2009[10]
- *ICCR dataset:* **iccr-cancer.org**
- *The Pathology Request-Test-Report Cycle — Guidelines for Requesters and Pathology Provider*[11]
- *World Health Organization Classification of Tumours*
- *AJCC Cancer Staging Manual, 7th edition*[12]
- *UICC Classification of Malignant Tumours, 7th edition*[13]

Changes since the last edition

<Insert text, as necessary>

Authority and development

Instructions for 'Authority and development'
Under 'Expert committee', list the members of the committee, giving the title, academic credentials, profession for each person, and adding 'Chair' and 'Lead author' in brackets after the appropriate name(s).
Under 'Stakeholders', list any stakeholders whose opinion was sought during the open consultation phase.
Under 'Secretariat', list the secretariat members for the protocol.
Under 'Development process', give details of the process used to develop the protocol, highlighting any deviations from the process outlined in *Guidelines for authors of structured cancer pathology reporting protocols*, and amend the text on evidence, if necessary.
Delete this box and its contents

This section provides information about the process undertaken to develop this protocol.

This <insert number of edition> edition of the protocol is an amalgam of two separate processes:

1. This protocol is based on the ICCR dataset *< insert specific name of dataset and specific revision>*. All ICCR elements from this dataset, both required (mandatory) and recommended (optional), are included in this protocol, verbatim. (It should be noted that RCPA feedback from all Anatomical Pathology fellows and specifically the local expert committee was sought during the development process of the ICCR dataset.) Details of the ICCR development process and the international expert authoring committee responsible for the ICCR dataset are available on the ICCR website: iccr-cancer.org.

2. Additional elements, values and commentary have been included as deemed necessary by the local expert committee. In addition, the standard inclusions of RCPA protocols eg example reports, request information etc, have also been added.

Local expert committee

<Insert text >

Acknowledgements

The *<Insert text about specific cancer >* expert committee wish to acknowledge the specific contributions of …….

Stakeholders

<Insert text >

Secretariat

<Insert text >

Development process

This protocol has been developed following the ten-step process set out in *Guidelines for Authors of Structured Cancer Pathology Reporting Protocols.*[14]

Where no reference is provided, the authority is the consensus of the local expert group for local inclusions and the ICCR Dataset Authoring Committee for ICCR components denoted with the ICCR logo.

1 Pre-analytical

Instructions for 'Pre-analytical
Amend the introductory text, if necessary.
Amend the standards, guidelines and commentary given below as required (e.g. change text, delete, change a standard to a guideline, etc), and adjust numbering as necessary.
Provide additional standards, guidelines and commentary, as necessary, for any specific features expected to be relevant for the specific cancer type.
Give a separate **standard** for any item that **must** be included
Give a separate **guideline** for any item that **should** or **may** be included
Add **commentary** to standards and guidelines as appropriate, and adjust numbering as necessary.
Complete Appendix 1 in this template, ensuring that it is consistent with the standards and guidelines given in this section. Further instructions are given in Appendix 1
Delete this box and its contents

This chapter relates to information that should be recorded on receipt of the specimen in the laboratory.

The pathologist is reliant on the quality of information received from the clinicians or requestor. Some of this information may be received in generic pathology request forms, however, the additional information required by the pathologist specifically for the reporting of <insert cancer name> is outlined in Appendix 1. Appendix 1 also includes a standardised request information sheet that may be useful in obtaining all relevant information from the requestor**.**

Surgical handling procedures affect the quality of the specimen and recommendations for appropriate surgical handling are included in Appendix 1.

S1.01 All demographic information provided on the request form and with the specimen must be recorded.

CS1.01a The Royal College of Pathologists of Australasia (RCPA) *The Pathology Request-Test-Report Cycle — Guidelines for Requesters and Pathology Providers* must be adhered to.[15] This document specifies the minimum information to be provided by the requesting clinician for any pathology test.

CS1.01b The patient's ethnicity must be recorded, if known. In particular whether the patient is of aboriginal or Torres Strait islander origin. This is in support of a government initiative to monitor the health of indigenous Australians particularly in relation to cancer.

CS1.01c The patient's health identifiers may include the patient's Medical Record Number as well as a national health number such as a patient's Medicare number (Australia), Individual Healthcare Identifier (IHI) (Australia) or the National Healthcare Identifier (New Zealand).

S1.02 All clinical information as documented on the request form must be recorded verbatim.

CS1.02a The request information may be recorded as a single text (narrative) field or it may be recorded atomically.

S1.03 The pathology accession number of the specimen must be recorded.

S1.04 The principal clinician involved in the patient's care and responsible for investigating the patient must be recorded.

CS1.04a Knowledge of the clinical presentation is an essential part of the WHO classification yet it may not be available for a number of reasons:

- The clinical assessment and staging may be incomplete at the time of biopsy.
- The pathology request is often authored by the clinician performing the biopsy rather than the clinician who is investigating and managing the patient.
- The identity of this clinician is often not indicated on the pathology request form

In practice therefore, it is important in such cases that the reporting pathologist should be able to communicate with the managing clinician for clarification.

CS1.04b The Australian Healthcare identifiers i.e. Healthcare Provider Identifier - Individual (HPI-I) and Healthcare Provider Identifier - Organisation (HPI-O) should be included, where possible, to identify the principal clinician involved in the patient's care.

G1.01 Any clinical information received in other communications from the requestor or other clinician should be recorded together with the source of that information.

2 Specimen handling and macroscopic findings

Instructions for 'Specimen handling and macroscopic findings'
Amend the introductory text, if necessary.
Amend the standards, guidelines and commentary given below as required (e.g. change text, delete, change a standard to a guideline, etc), and adjust numbering as necessary.
Include any macroscopic elements from the ICCR Dataset under Macroscopic findings. Structure each ICCR element as a standard or guideline using the applicable wording: 'must be recorded" or "should be recorded' The ICCR elements may be re-sequenced as necessary. The ICCR logo must be included against each standard (required element), guideline (recommended element) or commentary sourced from the ICCR Dataset. Each section, taken directly from the ICCR Dataset must be enclosed in a grey box as shown below.
After review of the macroscopic elements in the RCPA online Cut-up Manual, include any applicable elements under Macroscopic findings. Structure each element as a standard or guideline using the applicable wording: 'must be recorded" or "should be recorded'
Provide any additional standards, guidelines and commentary, as necessary, for any specific features relevant for the specific cancer type.
Give a separate **standard** for any item that **must** be included
Give a separate **guideline** for any item that **should** or **may** be included
Add **commentary** to standards and guidelines as appropriate, and adjust numbering as necessary.
Delete this box and its contents

This chapter relates to the procedures required after the information has been handed over from the requesting clinician and the specimen has been received in the laboratory.

Tissue Banking

- Pathologists may be asked to provide tissue samples from fresh specimens for tissue banking or research purposes. The decision to provide tissue should only be made if the pathologist is sure that the diagnostic process will not be compromised. As a safeguard, research use of the specimen may be put on hold until the diagnostic process is complete.

Specimen handling

- Detailed fixation and specimen handling instructions are available from the RCPA online Cut-up Manual:

  www.rcpa.edu.au/Library/Practising-Pathology/Macroscopic-Cut-Up

- *<Insert specific measures>* should be used in examination and block selection.

    - <Insert commentary here as necessary, or delete>.

Macroscopic findings

S2.0X **All measurements are in SI units, unless explicitly stated.**

S2.0X **The labelling of the specimen(s) must be clearly recorded.**

S2.0X	**<*Insert ICCR element*> must be recorded.**	
	CS2.0Xa	<Insert ICCR commentary if available.

S2.0X **<*Insert item to be described*> must be described.**

CS2.0Xa <Insert commentary here as necessary, or delete>.

G2.0X *<Insert specific measures>* should be described.

CG2.0Xa <Insert commentary here as necessary, or delete>.

G2.0X A block identification key listing the nature and origin of all tissue blocks should be recorded.

CG2.0Xa The origin/designation of all tissue blocks should be recorded. This information should be documented in the final pathology report and is particularly important should the need for internal or external review arise. The reviewer needs to be clear about the origin of each block in order to provide an informed specialist opinion. If this information is not included in the final pathology report, it should be available on the laboratory computer system and relayed to the reviewing pathologist.

Recording the origin/designation of tissue blocks also facilitates retrieval of blocks for further immunohistochemical or molecular analysis, research studies or clinical trials.

G2.0X A descriptive or narrative field should be provided to record any macroscopic information that is not recorded in the above standards and guidelines, and that would normally form part of the macroscopic description.

CG2.0Xa The traditional macroscopic narrative recorded at the time of specimen dissection is often reported separately from the cancer dataset. Although this remains an option, it is recommended that macroscopic information be recorded within the overall structure of this protocol.

CG2.0Xb Much of the information recorded in a traditional macroscopic narrative is covered in the standards and guidelines above and in many cases, no further description is required.

CG2.0Xc A traditional macroscopic description may be required when the Laboratory Information System (LIS) does not allow a structured approach.

CG2.0Xd Where the LIS offers an electronic interface for structured data entry the need for narrative can be significantly reduced to describe only information not otherwise captured.

3 Microscopic findings

Instructions for 'Microscopic findings'
Amend the introductory text, if necessary.
Amend the standards, guidelines and commentary given below as required (e.g. change text, delete, change a standard to a guideline, etc), and adjust numbering as necessary.
Include any microscopic elements from the ICCR Dataset. Structured each ICCR element as a standard or guideline using the applicable wording: 'must be recorded" or "should be recorded' The ICCR elements may be re-sequenced as necessary. The ICCR logo must be included against each standard (required element), guideline (recommended element) or commentary sourced from the ICCR Dataset. Each section, taken directly from the ICCR Dataset must be enclosed in a grey box as shown below.
Provide additional standards, guidelines and commentary, as necessary, for any specific features expected to be relevant for the specific cancer type.
Give a separate **standard** for any item that **must** be included
Give a separate **guideline** for any item that **should** or **may** be included
Add **commentary** to standards and guidelines as appropriate (e.g. to provide referenced explanatory notes on the use of the parameters specified), and adjust numbering as necessary.
Delete this box and its contents

Microscopic findings relates to purely histological (morphological) assessment. Information derived from multiple investigational modalities, or from two or more chapters of this protocol, are described in Chapter 5.

S3.0X ***<Insert specific finding>*** **must be recorded.**

CS3.0Xa <Insert commentary here as necessary, or delete>.

S3.0X	***<Insert ICCR element>*** **must be recorded.**	
	CS3.0Xa	<Insert ICCR commentary if available>.

G3.0X *<Insert specific measures>* should be recorded.

CG3.0Xa <Insert commentary here as necessary, or delete>.

G3.0X A descriptive or narrative field should be provided to record any microscopic information that is not recorded in the above standards and guidelines.

4 Ancillary studies findings

Instructions for 'Ancillary studies findings'
Amend the introductory text, if necessary. For example, if this chapter is not relevant to the specific cancer, add the following to the introductory text: 'Ancillary studies are not currently used on a routine basis for diagnosis, staging or management of <*insert cancer type here*>. '
Include any ancillary tests specified in the ICCR Dataset. Structured each ICCR element as a standard or guideline using the applicable wording: 'must be recorded' or 'should be recorded' The ICCR elements may be re-sequenced as necessary. The ICCR logo must be included against each standard (required element), guideline (recommended element) or commentary sourced from the ICCR Dataset. Each section, taken directly from the ICCR Dataset must be enclosed in a grey box as shown below.
Insert a subheadings for each class of ancillary test as applicable (e.g. 'Immunohistochemistry', 'Cytogenetics' or 'Flow cytometry').
Amend the text, standards, guidelines and commentary given below as required (e.g. change text, delete, change a standard to a guideline, etc), and adjust numbering as necessary.
Provide additional standards, guidelines and commentary, as necessary, for any specific features expected to be relevant for the specific cancer type.
Give a separate **standard** for any item that **must** be included
Give a separate **guideline** for any item that **should** or **may** be included
Add **commentary** to standards and guidelines as appropriate (e.g. to provide referenced explanatory notes on the use of the parameters specified), and adjust numbering as necessary.
Delete this box and its contents

Ancillary studies may be used to determine lineage, clonality or disease classification or subclassification; as prognostic biomarkers; or to indicate the likelihood of patient response to specific biologic therapies.

Some studies, such as Her-2 testing, are required under the Pharmaceutical Benefits Scheme, to enable certain specific therapies to be prescribed.

<Insert class of ancillary test here if applicable>

G4.0X	<*Insert ICCR element*> should be recorded.	
	CG4.0Xa	<Insert ICCR commentary if available>.

G4.0X <*Insert ancillary test*> should be performed and the results incorporated into the pathology report.

CG4.0Xa Ancillary tests performed externally may contain information needed for compliance with NPAAC and RCPA requirements, but that are not relevant to cancer reporting

protocols. The specific elements of an ancillary study report needed for cancer reporting include the following:

- laboratory performing the test
- substrate (e.g. cytology smears, fluid in special media, paraffin block, fresh tissue, etc)
- method (where relevant)
- results
- conclusion (usually a text field)
- person responsible for reporting the ancillary test.

CG4.0Xb Documentation of all relevant ancillary study findings is essential for overarching commentary (see Synthesis and Overview, Chapter 5), in which the significance of each finding is interpreted in the overall context of the case.

CG4.0Xc <Insert commentary here as necessary, or delete>

S4.0X <*Insert specific finding*> must be recorded.

CS4.0Xa <Insert commentary here as necessary, or delete>.

G4.0X <*Insert specific measures*> should be recorded.

CS4.0Xa <Insert commentary here as necessary, or delete>.

5 Synthesis and overview

Instructions for 'Synthesis'
Amend the introductory text, if necessary.
Include any 'synthesised' information specified in the ICCR Dataset such as staging. Structure each ICCR element as a standard or guideline using the applicable wording: 'must be recorded' or "should be recorded' The ICCR elements may be re-sequenced as necessary. The ICCR logo must be included against each standard (required element), guideline (recommended element) or commentary sourced from the ICCR Dataset. Each section, taken directly from the ICCR Dataset must be enclosed in a grey box as shown below.
Amend the standards, guidelines and commentary given below as required (e.g. change text, delete, change a standard to a guideline, etc), and adjust numbering as necessary.
Provide additional standards, guidelines and commentary, as necessary, for any specific features expected to be relevant for the specific cancer type. Include any data elements that are synthesized from more than one chapter.
Give a separate **standard** for any item that **must** be included
Give a separate **guideline** for any item that **should** or **may** be included
Add **commentary** to standards and guidelines as appropriate, and adjust numbering as necessary.
Delete this box and its contents

Information that is synthesised from multiple modalities and therefore cannot reside solely in any one of the preceding chapters is described here.

For example. *tumour stage* is synthesised from multiple classes of information – clinical, macroscopic and microscopic.

By definition, synthetic elements are inferential rather than observational, often representing high-level information that is likely to form part of the report 'Summary' or 'Diagnosis' section in the final formatted report.

Overarching case comment is synthesis in narrative format. Although it may not necessarily be required in any given report, the provision of the facility for overarching commentary in a cancer report is essential.

S5.01	**<*Insert ICCR element*> must be recorded.**	
	CS5.01a	<Insert ICCR commentary if available>.

S5.02 The tumour stage must be recorded according to the <*insert text here*> system <*insert version here*>

CS5.01a *<Insert commentary here as necessary, or delete>*

S5.03 The year of publication and edition of the cancer staging system used in S5.02 must be included in the report.

G5.02 The "Diagnostic summary" section of the final formatted report should include:

a. Specimen type (GXX)

b. Tumour site and laterality (GXX)

c. Tumour type (SXX)

d. Tumour grade (GXX)

e. Tumour stage (SXX)

f. Completeness of excision (SXX)

G5.0X <*Insert specific finding*> should be recorded.

CG5.0Xa <Insert commentary here as necessary, or delete>.

S5.0X The reporting system must provide a field for free text or narrative in which the reporting pathologist can give overarching case comment.

CS5.0Xa This field may be used, for example, to:
- list any relevant ancillary tests
- document any noteworthy adverse gross and/or histological features
- express any diagnostic subtlety or nuance that is beyond synoptic capture
- document further consultation or results still pending.

CS5.0Xa Use of this field is at the discretion of the reporting pathologist.

G5.0X The edition/version number of the RCPA protocol on which the report is based should be included on the final report.

CS5.0Xa For example, the pathology report may include the following wording at the end of the report: **"**the data fields within this formatted report are aligned with the criteria as set out in the RCPA document " XXXXXXXXXX" XXXX Edition dated XXXXXXX".

6 Structured checklist

Instructions for 'Structured checklist'
Amend the introductory text, if necessary.
Provide a structured reporting checklist that a pathologist can use as a guide to the reporting process.
Include in the checklist all relevant standards and guidelines detailed in the protocol
Indicate whether defined values or free text is required.
Indicate any pre-requisite or dependencies between elements.
The ICCR logo must be included against each standard (required element) and guideline (recommended element) sourced from the ICCR Dataset. Each section, taken directly from the ICCR Dataset must be enclosed in a heavier grey box (1.25 thick border) (normal thickness is 0.25).
Delete this box and its contents

The following checklist includes the standards and guidelines for this protocol which must be considered when reporting, in the simplest possible form. The summation of all "Standards" is equivalent to the "Minimum Data Set" for <cancer>. For emphasis, standards (mandatory elements) are formatted in bold font.

S6.01 The structured checklist provided below may be modified as required but with the following restrictions:

a. All standards and their respective naming conventions, definitions and value lists must be adhered to.

b. Guidelines are not mandatory but are recommendations and where used, must follow the naming conventions, definitions and value lists given in the protocol.

G6.01 The order of information and design of the checklist may be varied according to the laboratory information system (LIS) capabilities and as described in *Functional Requirements for Structured Pathology Reporting of Cancer* Protocols.[10]

CG6.01a Where the LIS allows dissociation between data entry and report format, the structured checklist is usually best formatted to follow pathologist workflow. In this situation, the elements of synthesis or conclusions are necessarily at the end. The report format is then optimised independently by the LIS.

CG6.01b Where the LIS does not allow dissociation between data entry and report format, (for example where only a single text field is provided for the report), pathologists may elect to create a checklist in the format of the final report. In this situation, communication with the clinician takes precedence and the checklist design is according to principles given in Chapter 7.

G6.02 Where the checklist is used as a report template (see G6.01), the principles in Chapter 7 and Appendix 2 apply

CG6.02a All extraneous information, tick boxes and unused values should be deleted.

G6.03 Additional comment may be added to an individual response where necessary to describe any uncertainty or nuance in the selection of a prescribed response in the checklist. Additional comment is not required where the prescribed response is adequate.

Format to be used for the checklist (excerpt from the Prostate, Radical Prostatectomy protocol, 2nd edition):

Item descriptions in italics are conditional on previous responses.

Values in all caps are headings with sub values.

S/G	Item description	Response type	Conditional
Clinical information and surgical handling			
S1.01	**Demographic information provided**		
S1.02	**Clinical information provided on request form**	**Text** OR **Structured entry as below:**	
	Surgical procedure	**Text**	
	Nature of specimen	**Text**	
	Clinical history (including Gleason grade and score of previous specimens)	**Text**	
	Previous therapy	**Text**	
	**Pre-biopsy serum PSA**	**Numeric: ____ ng/mL** **OR** **Not available**	
	Relevant clinical information for clinicopathological staging	**Text**	

S1.03	**Pathology accession number**	**Alpha-numeric**	
S1.04	**Principal clinician**	**Text**	
G1.01	Comments	**Text**	
Macroscopic findings			
S2.01	**Specimen weight (ie Prostate without seminal vesicles)**	**Numeric: _____g**	
G2.01	Specimen dimensions (prostate)	**Numeric: __x__x__mm**	
S2.02	**Seminal vesicles**	**Single selection value list:** • Absent • Present (partially or completely resected)	
S2.03	**Lymph nodes**	**Single selection value list:** • Absent • Present	**If present consider recording G2.02.**
G2.02	*Laterality*	***Single selection value list:*** • *Left* • *Right* • *Bilateral*	

7 Formatting of pathology reports

Instructions for 'Formatting of pathology reports'
Amend the introductory text, if necessary.
Provide a de-identified example report for the specific cancer type in Appendix 3.
Delete this box and its contents

Good formatting of the pathology report is essential for optimising communication with the clinician, and will be an important contributor to the success of cancer reporting protocols. The report should be formatted to provide information clearly and unambiguously to the treating doctors, and should be organised with their use of the report in mind. In this sense, the report differs from the structured checklist, which is organised with the pathologists' workflow as a priority. For an example pathology report, please refer to Appendix 3.

Uniformity in the format as well as in the data items of cancer reports between laboratories makes it easier for treating doctors to understand the reports; it is therefore seen as an important element of the systematic reporting of cancer. For guidance on formatting pathology reports, please refer to Appendix 2.

Appendix 1 Pathology request information and surgical handling procedures

This appendix describes the information that should be collected before the pathology test. Some of this information can be provided on generic pathology request forms; any additional information required specifically for the reporting of <insert cancer name> may be provided by the clinician on a separate request information sheet. An example request information sheet is included below. Elements which are in bold text are those which pathologists consider to be required information. Those in non-bold text are recommended.

Also included in this appendix are the procedures that are recommended before handover of specimens to the laboratory.

Patient information

- **Adequate demographic and request information should be provided with the specimen.**
  - Items relevant to cancer reporting protocols include:
    - patient name
    - date of birth
    - sex
    - identification and contact details of requesting doctor
    - date of request
  - The patient's ethnicity should be recorded, if known. In particular whether the patient is of aboriginal or Torres Strait islander origin. This is in support of a government initiative to monitor the health of indigenous Australians particularly in relation to cancer.
- The patient's health identifiers should be provided.
  - The patient's health identifiers may include the patient's Medical Record Number as well as a national health number such as a patient's Medicare number (Australia), Individual Healthcare Identifier (IHI) (Australia) or the National Healthcare Identifier (New Zealand).
- The Australian Healthcare identifiers i.e. Healthcare Provider Identifier - Individual (HPI-I) and Healthcare Provider Identifier - Organisation (HPI-O) should be use, where possible, to identify the requesting doctor.

Clinical Information

- **The anatomical site of the biopsy or resection should be recorded.**
  - Site is an important identifier when multiple biopsies are

performed.

- Sufficient information is required to localise the lesion for subsequent therapy. A diagram or photograph can facilitate this.

- Prognostic significance <Insert text or delete commentary>

➢ **The laterality of the lesion should be recorded.**

- Laterality information is needed for identification purposes.

➢ The clinical diagnosis or differential diagnosis should be recorded.

- Providing the provisional clinical diagnosis or differential diagnosis improves clinicopathological correlation and improves diagnostic accuracy.

➢ **The <*insert specific item*> should be recorded.**

- <Insert commentary here as necessary, or delete>.

➢ The <*insert specific item*> should be recorded.

- <Insert commentary here as necessary, or delete>.

➢ **Record if this is a new primary cancer or a recurrence of a previous cancer, if known.**

- The term recurrence defines the return, reappearance or metastasis of cancer (of the same histology) after a disease free period.

  Recurrence should be classified as distant metastases or regional (local) recurrence.

  Regional (local) recurrence refers to the recurrence of cancer cells at the same site as the original (primary) tumour or the regional lymph nodes.

  Distant metastasis refers to the spread of cancer of the same histologic type as the original (primary) tumour to distant organs or distant lymph nodes.

- This information will provide an opportunity for previous reports to be reviewed during the reporting process, which may provide valuable information to the pathologist. This information also has implications for recording cancer incidence and evidence based research.

Surgical handling

➢ The specimen should be capable of orientation if the status of specific surgical margins is critical in determining the need for, or extent of, further surgery.

- Where there are no anatomical landmarks, specimen orientation may be indicated with marking sutures or other techniques. If a specimen is orientated, the orientation should be indicated on the specimen request form (this may be facilitated by the use of a diagram).

- Identification of research sections should preferably be done in consultation with the pathologist in order to avoid compromising the diagnosis.

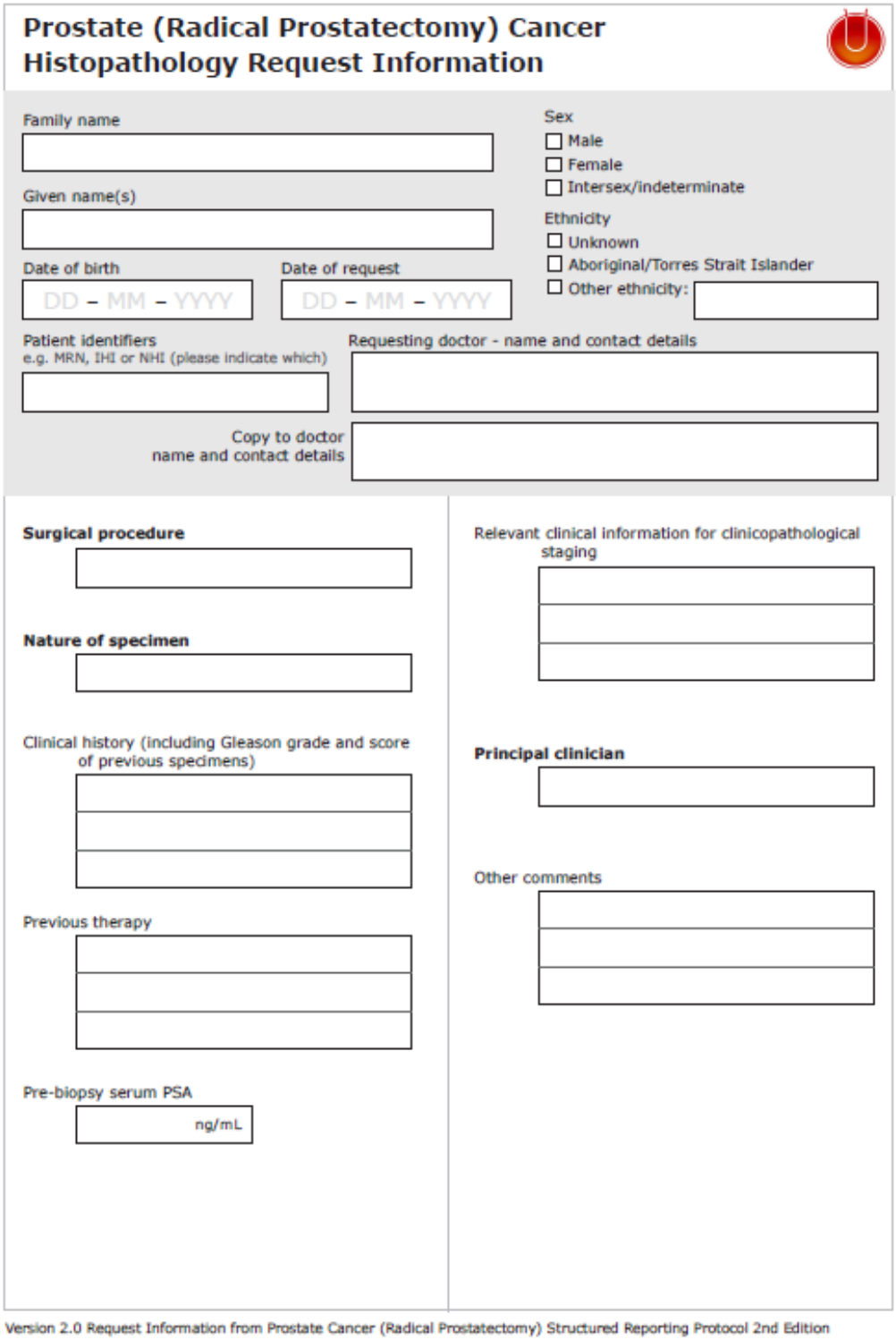
- ***<Insert specific measures>* should be taken when collecting specimens.**

  - <Insert commentary here as necessary, or delete>.

- *<Insert specific measures>* should be taken when collecting specimens.

  - <Insert commentary here as necessary, or delete>.

Example Request Information Sheet



Prostate (Radical Prostatectomy) Cancer Histopathology Request Information

Family name

Given name(s)

Date of birth DD – MM – YYYY

Date of request DD – MM – YYYY

Sex
- ☐ Male
- ☐ Female
- ☐ Intersex/indeterminate

Ethnicity
- ☐ Unknown
- ☐ Aboriginal/Torres Strait Islander
- ☐ Other ethnicity:

Patient identifiers
e.g. MRN, IHI or NHI (please indicate which)

Requesting doctor - name and contact details

Copy to doctor name and contact details

Surgical procedure

Nature of specimen

Clinical history (including Gleason grade and score of previous specimens)

Previous therapy

Pre-biopsy serum PSA ng/mL

Relevant clinical information for clinicopathological staging

Principal clinician

Other comments

Version 2.0 Request Information from Prostate Cancer (Radical Prostatectomy) Structured Reporting Protocol 2nd Edition

The above Request Information Sheet is published to the RCPA website

Appendix 2 Guidelines for formatting of a pathology report

Headings and spaces should be used to indicate subsections of the report, and heading hierarchies should be used where the Laboratory Information System (LIS) allows it. Heading hierarchies may be defined by a combination of case, font size, style and, if necessary, indentation.

- Grouping like data elements under headings and using 'white space' assists in rapid transfer of information.[16]

Descriptive titles and headings should be consistent across the protocol, checklist and report.

When reporting on different tumour types, similar layout of headings and blocks of data should be used, and this layout should be maintained over time.

- Consistent positioning speeds data transfer and, over time, may reduce the need for field descriptions or headings, thus reducing unnecessary information or 'clutter'.

Within any given subsection, information density should be optimised to assist in data assimilation and recall.

- Configuring reports in such a way that they 'chunk' data elements into a single unit will help to improve recall for the clinician. [16]
- 'Clutter' should be reduced to a minimum.[16] Thus, information that is not part of the protocol (e.g. billing information, SNOMED codes, etc) should not appear on the reports or should be minimized.
- Injudicious use of formatting elements (e.g. too much bold, underlining or use of footnotes) constitutes clutter and may distract the reader from the key information.

Where a structured report checklist is used as a template for the actual report, any values provided in the checklist but not applying to the case in question must be deleted from the formatted report.

Reports should be formatted with an understanding of the potential for the information to mutate or be degraded as the report is transferred from the LIS to other health information systems.

As a report is transferred between systems:

- text characteristics such as font type, size, bold, italics and colour are often lost
- tables are likely to be corrupted as vertical alignment of text is lost when fixed font widths of the LIS are rendered as proportional fonts on screen or in print
- spaces, tabs and blank lines may be stripped from the report, disrupting the formatting
- supplementary reports may merge into the initial report.

Appendix 3 Example of a pathology report

Citizen, George W.
C/O Paradise Close
Sunset Bay Resort
Nar Nar Goon East, 3181

Male

DOB 1/7/1951
MRN FMC1096785

Lab Ref: **13/P28460**
Referred: 30/2/2013

Copy to: Dr G. Gleason
Rainforest Cancer Centre.
46 Smith Road,
Woop Woop, 3478

Referred by: Dr V. Smith
Suite 3, AJC Medical Centre,
Bunyip Crescent
Nar Nar Goon West, 3182

RADICAL PROSTATECTOMY STRUCTURED REPORT Page 1 of 2

Diagnostic Summary

Radical prostatectomy:

Adenocarcinoma (Acinar);
Gleason score (ISUP 2005) 4+3 = 7, tertiary grade 5;
AJCC Stage T3a, N0, M0; PSM (R1).

Comment:
1. Focal urothelial carcinoma *in situ* (CIS) is noted in the prostatic urethra. The urethral resection margin appears clear.
2. Equivocal margin involvement (due to crush artefact) by prostatic adenocarcinoma is noted at the apex focally.

Supporting Information

CLINICAL

Surgical procedure:	Radical prostatectomy
Pre-biopsy serum PSA:	8.9 ng/mL
Clinical history:	No symptoms Previous biopsy: Gleason 3+3=6
Previous therapy:	Nil
Clinical stage:	No known metastases

MACROSCOPIC

Specimen weight:	23g without seminal vesicles
Specimen dimensions:	40 x 37 x 30mm
Seminal vesicles:	Present
Lymph nodes:	Present Right pelvic: 2 Left pelvic: 3

MICROSCOPIC

Histological tumour type:	Adenocarcinoma (Acinar, usual type)
Tumour location	
Largest nodule	
Located by quadrant:	Right anterior and right posterior.
Located by plane:	Apex and mid prostate. Focally crosses midline posteriorly.
Other nodules (>10mm)	
Located by quadrant:	Left posterior.
Located by plane:	Base of prostate. Smaller nodules are present.
Maximum size of dominant nodule:	22mm

References

Instructions for 'References'
References should be listed in the text in Vancouver (superscript, numbered) style: And listed in the final section as follows: 1 Cross SS, Feeley KM and Angel CA (1998). The effect of four interventions on the informational content of histopathology reports of resected colorectal carcinomas. *J Clin Oncol* 51(6):481–482. 2 Mathers M, Shrimankar J, Scott D, Charlton F, Griffith C and Angus B (2001). The use of a standard proforma in breast cancer reporting. *J Clin Pathol* 54(10):809–811. 3 Srigley JR, McGowan T, MacLean A, Raby M, Ross J, Kramer S and Sawka C (2009). Standardized synoptic cancer pathology reporting: A population-based approach. *J Surg Oncol* 99(8):517–524. 4 Gill AJ, Johns AL, Eckstein R, Samra JS, Kaufman A, Chang DK, Merrett ND, Cosman PH, Smith RC, Biankin AV and Kench JG (2009). Synoptic reporting improves histopathological assessment of pancreatic resection specimens. *Pathology* 41(2):161–167.
Delete this box and its contents

1 Merlin T, Weston A and Tooher R (2009). Extending an evidence hierarchy to include topics other than treatment: revising the Australian 'levels of evidence'. *BMC Med Res Methodol* 9:34.

2 Australian Cancer Network Colorectal Cancer Guidelines Revision Committee (2005). *Guidelines for the Prevention, Early Detection and Management of Colorectal Cancer*. The Cancer Council Australia and Australian Cancer Network, Sydney.

3 Maughan NJ, Morris E, Forman D and Quirke P (2007). The validity of the Royal College of Pathologists' colorectal cancer minimum dataset within a population. *British Journal of Cancer* 97(10):1393–1398.

4 RCP (Royal College of Pathologists) (2015). Datasets and tissue pathways. Available from: http://www.rcpath.org/index.asp?PageID=254.

5 CAP (College of American Pathologists) (2015). Cancer protocols and checklists. Available from: http://www.cap.org/apps/cap.portal?_nfpb=true&cntvwrPtlt_actionOverride=%2Fportlets%2FcontentViewer%2Fshow&_windowLabel=cntvwrPtlt&cntvwrPtlt%7BactionForm.contentReference%7D=committees%2Fcancer%2Fcancer_protocols%2Fprotocols_index.html&_state=maximized&_pageLabel=cntvwr online text.

6 Cross SS, Feeley KM and Angel CA (1998). The effect of four interventions on the informational content of histopathology reports of resected colorectal carcinomas. *J Clin Oncol* 51(6):481–482.

7 Mathers M, Shrimankar J, Scott D, Charlton F, Griffith C and Angus B (2001). The use of a standard proforma in breast cancer reporting. *J Clin Pathol* 54(10):809–811.

8 Srigley JR, McGowan T, MacLean A, Raby M, Ross J, Kramer S and Sawka C (2009). Standardized synoptic cancer pathology reporting: A population-based approach. *J Surg Oncol* 99(8):517–524.

9 Gill AJ, Johns AL, Eckstein R, Samra JS, Kaufman A, Chang DK, Merrett ND, Cosman PH, Smith RC, Biankin AV and Kench JG (2009). Synoptic reporting improves histopathological assessment of pancreatic resection specimens. *Pathology* 41(2):161–167.

10 Royal College of Pathologists of Australasia (2011). Functional Requirements for Laboratory Information Systems to support Structured Pathology Reporting of Cancer Protocols https://www.rcpa.edu.au/Library/Practising-Pathology/Structured-Pathology-Reporting-of-Cancer/Implementation.

11 RCPA (Royal College of Pathologists of Australasia) (2004). *The Pathology Request-Test-Report Cycle — Guidelines for Requesters and Pathology Providers*, RCPA, Surry Hills, NSW.

12 Edge SE, Byrd DR, Compton CC, Fritz AG, Greene FL and Trotti A (eds) (2010). *AJCC Cancer Staging Manual 7th ed.*, New York, NY.: Springer.

13 Sobin L, Gospodarowicz M, Wittekind C and International Union against Cancer (eds) (2009). *TNM Classification of Malignant Tumours*, Wiley-Blackwell, Chichester, UK and Hoboken, New Jersey.

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